

REMARKS

I. Status of the Claims

Claims 8-24, 26-29 and 39-41 are currently pending in this application and stand rejected. Claims 1-7, 25 and 30-38 have been cancelled. Claims 8, 11, 12, 17 and 19 are currently amended.

Support for the amendments to claims 8, 11, 12, 17 and 19 can be found, for example, at page 9, lines 17-20 of the specification. Exemplary compounds within the amended scope include Gibberellins A₃, A₄, and A₇. See, e.g., *Specification*, p. 23.

Accordingly, Applicants submit that no new matter has been added by these amendments.

II. Rejections Under 35 U.S.C. § 112, ¶ 1

A. Background

The Examiner has rejected claims 8, 11-24, 26-29 and 39-41 under 35 U.S.C. § 112, ¶ 1, as allegedly failing to comply with the enablement requirement. *Office Action*, p. 2. Applicants respectfully traverse this rejection.

The Examiner alleges that the specification does not “reasonably provide enablement for the treatment of diabetes with Gibberellins of Formula (1).” *Id.* The Examiner admits that the specification enables the treatment of diabetes with Gibberellin A3 and a mixture of Gibberellin A3 and A4/A7, but alleges that the treatment of diabetes with Gibberellins of formula (1) is not enabled due to the number of species encompassed by the claimed genus. *Id.* at pp. 2 and 4. Specifically, the Examiner contends that the biological activity of Gibberellin species comprising a C10-C19 lactone bridge “varies and is unpredictable” in view of *Reeve et al.* (hereinafter “Reeve”). *Id.* at p. 4.

Initially, Applicants note that claims 8, 11, 12, 17 and 19 have been amended to recite Gibberellin and Gibberellin conjugates that comprise a C10-C19 lactone bridge. The amended claims still cover the structural characteristics of the three exemplary Gibberellin compounds disclosed in the specification, but significantly reduce the number of Gibberellin species encompassed by the rejected claims.

B. The Reeve Article Fails to Establish the Unpredictability of the Claimed Genus

The Examiner alleges that based on Reeve, the biological activity of compounds encompassed by the pending claims is unpredictable. *Id.* In particular, the Examiner identifies Table 1 in Reeve as demonstrative of unpredictability. Applicants respectfully disagree and believe that the Examiner has mischaracterized and/or misinterpreted the results outlined in Table 1 of the Reeve article.

Reeve discusses the consistent efficacy of Gibberellins comprising a C₁₀-C₁₉ lactone bridge. In general, Reeve recognizes the association between biological activity and the compatibility between Gibberellins and receptors in plant systems. *J. Exper. Bot.*, 85:431-445, 431 (1974). For instance, Reeve concludes that “[t]he substitution of a δ-lactone or a δ-lactol for a γ-lactone *results in reduced activity*” in the barley aleurone assay. *Id.* (emphasis added).

Table 1 in the Reeve article summarizes the relative activities of forty exemplary Gibberellin compounds in five separate assays. The activity of each compound is rated on a scale of “very low/inactive” to “very high,” with three intermediate levels of activity. *Id.* at Table 1. Applicants believe that of the forty exemplary compounds disclosed in Table 1, eleven of them would be covered by the presently-amended claims (GA₁, GA₄, GA₅, GA₈, GA₁₀, GA₁₆, GA₂₀, GA₂₉, GA₃₁, GA₃₄ and GA₃₅). Applicants further note that

of these eleven compounds, five of them displayed activity in every assay they were tested in (GA₁, GA₄, GA₅, GA₁₆ and GA₃₅). Two exhibited activity in four of the five assays (GA₈ and GA₂₀), while two showed activity in three of five (GA₁₀ and GA₃₁). Out of the eleven compounds relevant to the pending claims, only 2 (GA₂₉ and GA₃₄) exhibited activity in less than three of the assays tested. Thus, the eleven Gibberellin compounds of Table 1 encompassed by the presently-amended claims displayed activity in nearly 80% of the total number of assays in which they were tested.

In conclusion, Table 1 in Reeve fails to provide adequate proof establishing unpredictability and that a person of ordinary skill in the art could not practice the claimed invention without undue experimentation. On the contrary, Table 1 actually provides strong evidence that Applicants' presently-amended claims exhibit *at least* some level of biological activity. Applicants further contend that the mere presence of a small number of "inoperative embodiments" in a claimed invention is not grounds for an enablement rejection. M.P.E.P. §2164.08(b); *see also In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) (concluding that screening many hybridomas to find the few that fell within the claims was not undue experimentation). Reeve's Table 1 provides compelling evidence that Gibberellins comprising a C10-C19 lactone bridge exhibit, at the very least, a predictable basal level of biological activity.

C. The Conjugates of Biologically-Active Gibberellins Encompassed by the Pending Claims Would Predictably Yield the Biologically-Active Gibberellin *in vivo*

The Examiner further rejects claims 8, 11-24, 26-29 and 39-41 under 35 U.S.C. § 112, ¶ 1, because the pending claims allegedly encompass Gibberellin conjugates not described in the specification. *Office Action* at p. 4. In particular, the Examiner asserts

that the present claims encompass various glycoside ethers, the activity of which a person of ordinary skill in the art would not have been able to predict at the time of the invention. *Id.* Applicants respectfully disagree for at least the following reasons.

The Federal Circuit has ruled that a genus may be enabled “by showing the enablement of a representative number of species within the genus.” *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997) (emphasis added). “For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art ...would expect the claimed genus could be used in that manner without undue experimentation.” M.P.E.P. §2164.02 (emphasis added); see also *In re Grimme*, 274 F.2d 949 (C.C.P.A. 1960). “Proof of enablement will be required for other members [of a claimed genus] only where adequate reasons are advanced by the examiner to establish that a person skilled in the art *could not use the genus as a whole without undue experimentation.*” M.P.E.P. § 2164.02 (emphasis added).

Sembdner *et al.* (hereinafter “Sembdner”) recognized that Gibberellins were known in plants to occur both in the “free” and “conjugated” form. *Acta Universitatis Nicolai Copernici, Nauki Matematyczno-Przyrodnicze* 37:177-181, 177 (1976). Sembdner also notes that naturally-occurring acetate and glucoside conjugates, including the glucosidic ester conjugate of GA₄, had been isolated as early as 1973 *Id.* at p. 177. Around that same time, Hirada reported the synthesis of glucosidic conjugates of GA₃ and GA₄. *Id.* Sembdner explicitly states that “the measurable biological activity of [Gibberellin] glucosides depends on their enzymatical hydrolysis” by β-glucosidase. *Id.*

at pp. 178 and 180. "This conclusion was confirmed by the results with GA₁ and GA₃ glucosides . . . in sterile and nonsterile bioassay systems." *Id.*

Kren et al. (hereinafter "Kren") discusses the role of the glycosidic residue in the biological activity of several classes of compounds. *Current Med. Chem.*, 8:1313-38, 1313 (2001). According to Kren, "it is nearly impossible to define the general pattern of biological activities of the glycosides compared to their respective aglycons" (un-glycosylated parent compounds). *Id.* However, Kren goes on to state that "[a]n important aspect for prediction of glycoconjugate activities is . . . their susceptibility towards glycosidic cleavage." *Id.* Kren further explains that "in the stomach and in the intestine most glycosides are hydrolyzed, either by the acidic environment (stomach) or by the action of glycosidases (small intestine)." *Id.* Glycosidases also occupy bodily fluids such as blood serum.¹

Finally, as noted previously by Applicants, U.S. Patent No. 5,580,857 to Oden exemplified the efficacy of Gibberellins comprising a C10-C19 lactone bridge in mammalian systems. Oden has recognized the general efficacy of Gibberellin conjugates. *Oden* at col. 8, ll. 55-6 ("[t]he activity of gibberellin conjugates depends on the hydrolysis to free gibberellins"). According to Oden, the activity of Gibberellin conjugates in mammalian systems can be traced to the "enzymatic cleavage by e.g. glucosidase or by extreme pH values." *Id.* at col. 8, ll. 6-10.

Therefore, contrary to the Examiner's assertions, the combined teachings of Sembder, Kren and Oden teach that a wide variety of Gibberellin glycosides may be

¹ "Glycosidases" and "glucosidases" are terms that are often used interchangeably. Glycosidases refer generally to enzymes that cleave glycosidic bonds, while glucosidases refer more specifically to glycoside hydrolase enzymes that cleave individual glycosyl residues.

synthesized and administered to mammals to yield their respective aglycons *in vivo*. In particular, Sembner demonstrates that the biological activity of Gibberellin glucosides is anything but unpredictable by showing that in plants such compounds are readily metabolized by glucosidases to yield the parent Gibberellin. Oden teaches that similar hydrolytic activities take place in mammalian systems, where acid or enzyme-catalyzed hydrolysis facilitates the metabolism of Gibberellin glucoside conjugates. Kren further supports the teachings of Oden by identifying the general susceptibility of glucosidic compounds to hydrolytic degradation via acidity and/or enzymatic activity in the intestine and other bodily fluids.

In view of these combined teachings, Applicants respectfully contend that a person of ordinary skill in the art would readily expect Gibberellin glycosides to yield their parent Gibberellin aglycons *in vivo*. This fact, coupled with the synthetic and screening methods disclosed by Applicants, would allow the skilled artisan to determine the efficacy of the claimed Gibberellin compounds and accurately predict the biological effectiveness of their corresponding glycosidic conjugates without undue experimentation. See, e.g., *Cellpro, infra*. In addition, the knowledge generally available at the time the application was filed would allow a person of ordinary skill to synthesize and individually screen the claimed Gibberellin conjugates for their biological efficacy. Accordingly, Applicants' disclosure in view of the skilled artisan's knowledge would have enabled the skilled artisan to make and use the Gibberellin conjugates encompassed by presently-amended claims at the time the application was filed without undue experimentation.

D. Even If That the Field of the Invention is Unpredictable, the State of the Prior Art and Applicants' Disclosure Would Provide a Person of Ordinary Skill Adequate Guidance to Practice the Full Scope of the Claimed Invention

According to the Examiner, "[b]ecause there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, *an extraordinary amount of trial and error experimentation* is required to identify the active compounds." *Office Action* at p. 4. (emphasis added). Applicants respectfully disagree.

Even in an unpredictable art, the breadth of a claimed genus may still be enabled if factors such as "the state of the art" and "the relative skill of those in the art" weigh in Applicants' favor. *Ex parte Kubin*, 83 USPQ2d 1410, 1416 (Bd. Pat. App. & Inter. 2007) (concluding that the other *Wands* factors must be considered even though molecular biology is generally an unpredictable art). These factors may be evidenced by the prior art teachings and Applicants' disclosure. *Id.* Even if the amount of experimentation to practice the full scope of the claimed invention is extensive, *it will not be considered undue* if the techniques used to do so are routine and well known in the art:

The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

Johns Hopkins Univ. v. Cellpro, Inc., 47 USPQ2d 1705, 1719 (Fed. Cir. 1998) (emphasis added) (citing *PPG Indus., Inc. v. Guardian Indus. Corp.*, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996)).

The person of ordinary skill and more particularly, that person's level of skill, was an important factor in *Daiichi Sankyo Co. v. Apotex, Inc.*, 84 USPQ2d 1285 (Fed. Cir. 2007). Although this case addressed the issue of obviousness under 35 U.S.C. § 103, the court provided a variety of factors that should be evaluated when determining the level of ordinary skill, including

(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.

Id. at 1286-1287.

However, the court focused its analysis on the educational level of the inventors coupled with the fact that others working in the field "were of the same skill level." *Id.* The court's ultimate ruling hinged on this factual conclusion.

Applicants believe that a person of ordinary skill in the art of the present invention would be well-versed in the fields of chemistry and/or biochemistry. In addition, Applicants contend that those working in the field would generally possess a high degree of expertise in the field of drug development as it relates to diabetes and diabetic treatment. For example, Dr. Peter Jenkins, one of the named inventors of the instant application, has over thirty years of experience as a medical practitioner, including the management of patients with diabetes. See *Declaration of Dr. Peter Jenkins filed February 12, 2004*. Based on the instant invention and its related technologies, it is readily apparent that a high degree of sophistication and a sustained level of time-intensive research is needed to effect continued innovation. For at least these reasons, Applicants submit that the level of ordinary skill in view of the instant

application would include individuals with an advanced training in the field of medicine, organic chemistry, medicinal chemistry, or possibly biochemistry.

In the present case, Applicants have provided a method by which the skilled artisan can isolate various Gibberellins and test the efficacy of those compounds. For example, pages 2 and 3 of the specification provide references that teach methods of extracting and isolating naturally-occurring Gibberellins. The disclosure also provides references that teach synthetic methods for producing compounds encompassed by the presently-amended claims, including semi-synthetic and total-synthetic routes to derivatives of naturally-occurring Gibberellins. *Specification* at pp. 2-3. Finally, Applicants have provided *in vivo* assays used for detecting the efficacy of Gibberellins in treating diabetes and diabetes-related disorders. *Id.* at pp. 22-23.

Even assuming, for argument's sake, that identifying the active Gibberellin compounds of the presently-amended claims required "an extraordinary amount of trial and error," Applicants respectfully contend that this fact alone would not adequately support a rejection of the claims under Section 112, ¶ 1. See, e.g., *Cellpro, supra*. Accordingly, based on the high level of skill ordinary in the art and the teachings provided in the specification, Applicants contend that a skilled artisan would be sufficiently enabled to practice the full scope of the claimed invention.

III. Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 8-24, 26-29 and 39-41 under 35 U.S.C. § 103(a), as allegedly being obvious in view of the combined teaching of Wu (U.S. Patent No. 6,121,317), Boykin (U.S. Patent No. 6,312,663), and Lindenbaum (U.S.

Patent No. 5,591,709). *Office Action* at pp. 4-6. Applicants respectfully traverse this rejection.

In making a rejection under 35 U.S.C. § 103, the Examiner bears the initial burden to establish a *prima facie* case of obviousness. *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter.); *see also* M.P.E.P. § 2142. To meet this burden, the Examiner must point to some “need or problem known in the field of endeavor at the time of the invention and addressed by the patent” that would have provided a person of ordinary skill in the art a “reason for combining the elements in the manner claimed.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). “[A] design need or market pressure to solve a problem” may provide the requisite motivation to combine the claimed elements if a person of ordinary skill pursues a predictable solution that eventually leads to the anticipated success. *Id.* at 1740-41.

Nevertheless, the Federal Circuit recently stressed that the teaching, suggestion, or motivation (“TSM”) test retains an important role in obviousness analyses. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 83 USPQ2d 1169, 1174 (Fed. Cir. 2007). The court stated that “[a]s long as the [TSM] test is not applied as a ‘rigid and mandatory’ formula, that test can provide ‘helpful insight’ to an obviousness inquiry. *Id.* (quoting *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1731 (2007)). Moreover, the Federal Circuit stated that the Court in *KSR* “acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in a way the claimed new invention does’ in an obviousness determination.” *Id.*

In addition, the Examiner must show that the prior art references teach or suggest all the claim limitations. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Thus, assuming that an Examiner has correctly concluded that one of ordinary skill in the art would have seen a benefit in combining the prior art references, a rejection under 35 U.S.C. § 103 will fail if the Examiner has not established the presence of each and every claim limitation. See, e.g., *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (Bd. Pat App. & Inter. 1990).

A. Claims 8-10

The Examiner has rejected claims 8-10 under 35 U.S.C. § 103(a) over Boykin in view of Wu. *Office Action* at p. 5. The Examiner alleges that Boykin “discloses that impaired wound healing is associated with diabetes,” while Wu discloses “the treatment of wounds with a combination of gibberellins and antibiotics.” *Id.* Thus, according to the Examiner, “it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made to use a combination of gibberellins and anti-infective agents for the treatment of wounds which . . . result from [the] complication[s] of diabetes.” *Id.* Applicants respectfully disagree and traverse the rejection for at least the following reasons.

Boykin allegedly teaches methods and kits for “predicting the wound healing ability of diabetic patients based on levels of nitric oxide related products such as nitrate or nitrite in urine or other specimens.” *Boykin*, abstract. Boykin does not disclose the use of Gibberellins. Wu, on the other hand, allegedly teaches the use of Gibberellins for ulcer healing, surgical-wound healing and the cultivation of skin cells. *Wu*, col. 1, ll. 60-

64. However, the combination of Wu and Boykin fails to teach or suggest each and every limitation of Applicants' presently-amended claims.

Applicants note that the Examiner's present argument is similar to an earlier rejection set forth in the Office Action dated November 5, 2005, which was successfully traversed by Applicants in their response of February 6, 2006. In that case, the Examiner rejected the pending claims as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Davis et al., *Journal of the American Podiatric Medical Association* (1989) 79:1, 24-26 ("Davis"). *Office Action dated November 5, 2005*, p. 5. Although Davis did not teach or suggest the treatment of diabetes itself, the Examiner alleged that the treatment of diabetes was inherent in that reference because Davis administered Gibberellins to diabetic mice displaying "poor healing and anti-inflammatory capabilities." *Id.* In response, Applicants argued that a concomitant reduction in blood glucose did not "necessarily flow" from a decrease in inflammation because no direct correlation exists between a change in inflammation level and the same individual's blood glucose levels. See *Response dated February 6, 2006*, pp. 36-38. This argument was found to be persuasive, as the Examiner declined to renew this rejection in view of Davis in the subsequent Office Action dated March 6, 2006.

A *prima facie* case of obviousness for a claimed chemical compound requires a showing of structural similarity between the prior art compound and the claimed compound, as well as a showing that the *prior art would have suggested making specific molecular changes* necessary to achieve the claimed invention. *Takeda Chem. Indus., Ltd.*, 83 USPQ2d at 1174 (emphasis added). In the instant case, Wu fails to

teach the specific scope of Gibberellin compounds used in the methods of Applicants' presently-amended claims. In particular, Wu fails to disclose Gibberellins comprising substituents other than hydrogen at carbon 1 (carbon 4 in Wu). Additionally, the embodiments disclosed in Wu do not include glycoside ether derivatives, which are specifically claimed by Applicants in the instant application.

Moreover, claims 8-10 are specifically directed to "a method of treatment for diabetes and its complications and associated conditions." Thus, any references used to reject claims 8-10 necessarily require a teaching that Gibberellins can be used to treat diabetes in addition to its resulting conditions. However, neither Wu or Boykin teach or suggest the use of Gibberellins to treat diabetes. The disclosures in both references are limited to subject matter related to inflammation and impaired wound healing. Accordingly, a rejection under Section 103 over Boykin in view of Wu is improper because neither reference teaches or suggests each and every element of the presently-amended claims.

Here, Boykin notes that non-healing low extremity ulcerations (LEU) are "poorly understood." *Boykin* at col. 1, ll. 31-32. Boykin also teaches that nitric oxide (NO) is a primary regulator in wound healing, and that a "systematic deficiency of endothelial-derived NO has been observed in diabetics." *Id.* at col. 1, ll. 45-52. However, Boykin fails to explicitly or implicitly teach or suggest the use of Gibberellins in treating diabetes. In addition, Boykin fails to expressly or inherently disclose that a direct correlation exists between wound treatment and blood glucose levels. Particularly, Boykin fails to teach that effectively treating wounds resulting from diabetes will also yield a proportionate decrease in blood glucose levels.

Wu fails to suggest the use of Gibberellins to specifically treat wounds related to diabetes or elevated blood glucose levels. Wu merely suggests that Gibberellins possess activity as promoters of wound healing “possibly by stimulating cell division, hastening circulation, or promoting repairing.” *Wu*, col. 2, ll. 49-52. Thus, Wu fails to explicitly or implicitly teach the treatment of diabetes-related wounds. In addition, Wu fails to teach or suggest that Gibberellins could be used to treat diabetes and its associated conditions, or that effectively treating diabetic ulcers will inherently result in decreased blood glucose levels of the patient.

In conclusion, neither Boykin or Wu teach or suggest the use of Gibberellins for treating diabetic wounds. Nor does either reference establish a causal link between the direct treatment of diabetic wounds and decreased blood glucose levels. Although the ability to lower blood glucose levels may result in increased wound healing, it cannot be said that effectively treating a diabetic wound will necessarily result in decreased blood glucose levels. Finally, the disclosure in Boykin is directed to kits useful in detecting decreased levels of NO in diabetics, while Wu focuses on the treatment of non-diabetic wounds with Gibberellins. Therefore, a person of ordinary skill in the art would not be motivated to combine the disparate teachings of Boykin and Wu to arrive at the presently-claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 8-10 under Section 103 be withdrawn.

B. Claims 11-15, 40 and 41

The Examiner has also rejected claims 11-15, 40 and 41 under Section 103 as being unpatentable over Boykin in view of Wu and Lindebaum. *Office Action* at pp. 5-6. According to the Examiner, Lindenbaum discloses “the use of insulin or growth factors

for wound healing." *Id.* at p. 6. This teaching, in view of Wu and Boykin, would allegedly provide a person having ordinary skill in the art to "combine gibberellins with insulin or growth factors and use the resulting composition for treating wounds which are the results of complications for diabetes." Applicants respectfully disagree and traverse the rejection.

For reasons similar to those set forth above, Applicants submit that the combined teachings of Boykin, Wu and Lindenbaum fail to teach or suggest each and every limitation of the presently-amended claims. While Boykin and Lindenbaum do not teach or suggest the use of Gibberellins in treating diabetes, Wu fails to describe or suggest the specific scope of Gibberellin compounds used in the methods of Applicants' presently-amended claims.

Additionally, Applicants contend that the skilled artisan would not look to Lindenbaum when attempting to arrive at the instant claims. Lindenbaum allegedly discloses compositions and methods for treating wounds, including the use of anabolic hormones in a cellular nutrient medium. *Lindenbaum*, abstract. Lindenbaum altogether fails to teach the use of such combinations for treating diabetic wounds, let alone the use of those compositions in combination with Gibberellins. Lindenbaum specifically limits the scope of its invention to "skin wounds," which are "defined . . . as a breach in the continuity of the skin tissue which is caused by direct injury to the skin." *Id.* at col. 4, II. 42-46 (emphasis added). Thus, the teachings of Lindenbaum are related only to the treatment of wounds caused by external trauma, and not those caused or exacerbated by a biological condition such as diabetes. Accordingly, Applicants submit that this

skilled artisan would not be motivated to combine the teachings of Boykin, Wu and Lindenbaum to arrive at the presently-amended claims.

C. Claims 17-24 and 26-29

The Examiner has also rejected claims 17-24 and 26-29 under Section 103 as being unpatentable over Wu in view of Lindebaum. *Office Action* at pp. 5-6. The Examiner admits that Wu “does not disclose the use of gibberellins in combination with insulin or other growth factors.” *Id.* at p. 6. However, the Examiner attempts to cure this deficiency by combining Wu with Lindenbaum. The Examiner alleges that Lindenbaum discloses “the use of insulin and growth factors for wound healing.” *Id.* Applicants respectfully disagree and traverse the rejection.

For reasons similar to those set forth above, neither Wu or Lindenbaum teach or suggest the use of Gibberellins to treat diabetes, much less an anti-diabetic agent as claimed. Moreover, neither reference explicitly or implicitly teaches an anti-diabetic agent comprising Gibberellins for treating diabetic wounds. In fact, Lindenbaum limits the scope of its invention to wounds that are caused specifically by a direct, external trauma to the skin. Finally, neither Wu or Lindenbaum suggests the treatment of diabetic wounds with anti-diabetic agents comprising Gibberellins. For at least these reasons, a person of ordinary skill in the art would not be motivated to combine the teachings of Wu and Lindenbaum to arrive at the instant claims. Accordingly, Applicants respectfully request the withdrawal of the rejection under Section 103.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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